



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

JUN 09 2016

OFFICE OF  
RESEARCH AND DEVELOPMENT

The Honorable Lamar Smith  
Chairman  
Committee on Science, Space and Technology  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for your May 10 and June 2, 2016, letters to Gina McCarthy, Administrator of the U.S. Environmental Protection Agency, regarding the EPA's Integrated Risk Information System (IRIS) Program. Because the IRIS Program is managed by the Office of Research and Development, your letter was forwarded to me for response.

The IRIS Program plays an important role in supporting the agency's mission to protect public health. IRIS assessments provide information about the potential health effects that may result from exposure to environmental contaminants, such as chemicals in drinking water, pollutants in air, and contaminants in soil. IRIS assessments are not regulations, but they provide a critical part of the scientific foundation for decisions to reduce potential risks in the environment and protect public health.

The agency takes seriously the recommendations provided by the National Research Council (NRC) in their 2011 and 2014 reports.<sup>1</sup> According to the NRC, we have made considerable progress with implementing their recommendations and we continue to work hard to improve the efficiency and transparency of the IRIS Program. We are committed to making sure that the agency, state and local governments, and the American public have the most rigorous, science-based information about the health effects of chemicals in the environment.

The 2011 NRC report made several recommendations to improve the IRIS Program and IRIS assessments. While acknowledging that some of the recommendations would require a multi-year effort, the EPA took immediate steps to begin addressing these recommendations. We started by establishing, at all levels, strong management direction and support for approaches designed to increase the IRIS Program's productivity and transparency. Some examples of these activities include establishing an IRIS Executive Review Committee to provide review of assessments by senior scientists and managers from across the National Center for Environmental Assessment (NCEA); forming discipline-specific workgroups to streamline and manage workflow; instituting the scoping and problem formulation process early in assessment development, and holding regular public science meetings (the first major stakeholder meeting was held in November 2012). These changes were a critical part of the agency's efforts to fully address the 2011 NRC recommendations. Another step taken by the program was to introduce IRIS stopping rules (one of the topics of your documentation request). The stopping rules

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<sup>1</sup> The NRC's *Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde* (2011) and *Review of EPA's Integrated Risk Information System (IRIS) Process* (2014), are available online at [www.nap.edu](http://www.nap.edu).

outlined the EPA's criteria and process for the inclusion of new research without delaying IRIS assessments.

The changes we have implemented have made a difference and have been noticed. In 2014, as noted in your letter, the NRC completed a review of the IRIS assessment development process and the changes the EPA has made to the program. Their report commended the EPA's efforts to improve IRIS, stating:

Overall, the committee finds that substantial improvements in the IRIS process have been made, and it is clear that EPA has embraced and is acting on the recommendations in the NRC formaldehyde report. The NRC formaldehyde committee recognized that its suggested changes would take several years and an extensive effort by EPA staff to implement. Substantial progress, however, has been made in a short time, and the present committee's recommendations should be seen as building on the progress that EPA has already made.

The 2014 recommendations are not reiterating concerns from the 2011 report, but rather extending and building upon the recommendations of the 2011 report to further improve the quality, transparency, and efficiency of the IRIS Program. The 2014 NRC report also acknowledged ORD management's commitment to the IRIS Program, and the impact of key leadership positions within NCEA. The report notes:

The committee is confident that there is an institutional commitment to completing the revisions of the process, even as the program continues through the current transition phase and is closely watched by both stakeholders and Congress.

Echoing these observations, the Government Accountability Office (GAO) in the 2015 High Risk Report<sup>2</sup> determined that the EPA had fulfilled the criteria for demonstrating leadership commitment to *Transforming EPA's Processes for Assessing and Controlling Toxic Chemicals*, in part due to EPA leadership's public commitment to improving the IRIS Program. The EPA acknowledges that there is more work to do to meet the other criteria for resolving the high risk designation and is moving forward with efforts to address outstanding GAO concerns. I want to assure you that the EPA takes the NRC and GAO findings seriously and we are moving forward to implement those recommendations as expeditiously as possible. We continue to work to address the longer-term NRC recommendations, such as the application of systematic review methodologies.

I can also assure you that the EPA is committed to ensuring that there is transparency in the development of IRIS assessments. The IRIS Program has undertaken several activities over the last few years to foster transparency and increase opportunity for public and stakeholder input to the assessment development process. Those activities include:

- *Public Science Meetings held prior to the release of a draft assessment for peer review.* This includes opportunities for input at the earliest stages of assessment development (the scoping and problem formulation step), as well as later the opportunity to comment on a complete public comment draft of the assessment. In both cases, input received during these meetings may inform the development of the assessment. Additionally, the public and stakeholders have the opportunity to comment on the peer review draft of an assessment as part of the peer review

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<sup>2</sup> GAO's *High-Risk Series: An Update* (2015) is available at: <http://www.gao.gov/products/GAO-15-290>.



process managed by the Science Advisory Board Chemical Assessment Advisory Committee (SAB CAAC).

- *The implementation of systematic review in the assessment development process and accompanying changes to the format of IRIS assessments.* The systematic review process leads to better descriptions of literature searches and study evaluation so stakeholders can more readily see how decisions are made in an assessment. Corresponding improvements to the presentation of data in evidence tables, and streamlined syntheses of hazard information have improved the clarity of our documents. The SAB CAAC has noted these improvements in reviews of assessments<sup>3</sup> that have gone to peer review since the IRIS Program began adapting systematic review principles to assessment development.
- *The release of the IRIS Multi-Year Agenda.* Developed through a consensus process with the input of EPA program and regional offices, the multi-year agenda provides greater transparency to stakeholders by identifying the highest priority chemicals for upcoming assessments.
- *Improved communication with the public.* As part of its commitment to improve stakeholder outreach, the IRIS Program has increased communications with the public, including through significant updates to the website to be more informative and easier to navigate; the addition of a general comments docket for stakeholders to provide cross-cutting programmatic comment and feedback; and the use of e-mail distribution lists and social media.

You note in your May 10, 2016, letter the EPA's recent decision to no longer announce the availability of draft IRIS assessments for public comment in the Federal Register.<sup>4</sup> The intent of this decision was to increase transparency by shifting our communication about the availability of draft assessments to other commonly used communication mechanisms, such as our recently enhanced website and our established Listservs that provide regular updates on activities in the IRIS Program. The goal of this was to make the information more – rather than less – accessible to our stakeholders and the public. However, in response to your concerns, the EPA will continue to use the Federal Register to announce the availability of draft IRIS assessments for public comment. I hope this further assures you of the EPA's commitment to transparency and openness.

Enclosed with this letter is an initial set of documents responsive to your letter of May 10, 2016. Please note that portions of your request examine internal deliberations of an Executive Branch agency, the EPA, and, as such, raise a confidentiality interest. In order to identify specific documents in which the EPA has a confidentiality interest, we have added a watermark to these documents that reads "Internal Deliberative Document of the U.S. Environmental Protection Agency; Disclosure Authorized Only to Congress for Oversight Purposes." Through this accommodation, the EPA does not waive any confidentiality interests in these documents or similar documents in other circumstances. The EPA respectfully requests that the Committee and staff protect the documents and the information contained in them from further dissemination. Should the Committee determine that its legislative mandate requires further distribution of this confidential information outside the Committee, we request that such

<sup>3</sup> *Science Advisory Board Review of the IRIS Draft Toxicological Review of Trimethylbenzenes*, available at:

<http://yosemite.epa.gov/sab/sabproduct.nsf/c91996cd39a82f648525742400690127/ce1e280e77586de985257b65005d37c7!OpenDocument&TableRow=2.3#2>.

*Science Advisory Board Review of the IRIS Draft Toxicological Review of Ammonia*, available at: <http://yosemite.epa.gov/sab/SABPRODUCT.NSF/b5d8a1ce9b07293485257375007012b7/2fc334c0bec7a3cf85257b65005c500b!OpenDocument&TableRow=2.3#2>.

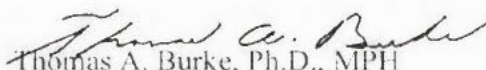
<sup>4</sup> 81 FR 18625, available online at: <https://federalregister.gov/a/2016-07181>.

need first be discussed with the agency to help ensure the Executive Branch's confidentiality interests are protected to the fullest extent possible.

We have initiated an electronic search to locate additional documents responsive to your request.

Again, thank you for your letter. If you have further questions, you may contact me or your staff may contact Christina Moody in the EPA's Office of Congressional and Intergovernmental Relations at (202) 564-0260 or moody.christina@epa.gov.

Sincerely,

  
Thomas A. Burke, Ph.D., MPH  
EPA Science Advisor and  
Deputy Assistant Administrator

Enclosures

cc: The Honorable Eddie Bernice Johnson  
Ranking Member